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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,697	04/10/2002	Thomas Wechsler	218090US6PCT	8632
22850	7590	10/08/2003		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER BEISNER, WILLIAM H	
			ART UNIT 1744	PAPER NUMBER

DATE MAILED: 10/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/030,697

Applicant(s)

WECHSLER ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 April 2002 (Pre. Amd.).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

2. The information disclosure statement filed 14 Jan. 2002 has been considered and made of record.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 17-20, 22-27 and 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katinger et al.(DE 0155237).

The reference of Katinger et al. discloses a bioreactor device that includes a housing (4,5); a receiving device (1) with a receiving space with at least two wall elements (A,B) that enclose the receiving space and each have a membrane. The receiving space includes a carrier element (25) that is permeable to the nutrient medium and is configured as a fabric for an adhesion of cells thereto. The carrier element also functions as a supporting fabric for the membranes. The housing is constructed as a flat cell having annular carrier plates (See Figure 9).

While the reference of Katinger et al. discloses that the fabric for supporting the membrane functions additionally as a carrier for the cells, the instant claims differ by reciting that the carrier fabric for the cells is an additional element with respect to the membrane supporting fabric.

The reference of Katinger et al. discloses that the receiving space can be between .3-10mm and that it is desirable to fill the entire space with carrier fabric (See page 7 of the English language translation).

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In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the receiving space with additional carrier material for the known and expected result of filling the entire receiving space with carrier material even when the membranes and support material are spaced such that the support material on the membranes do not completely fill the culture chamber.

With respect to claim 18, the carrier material has a 3-D structure.

With respect to claim 19, the reference discloses the use of a fabric net (See pages 7-8 of the translation).

With respect to claim 20, based merely on the material of the fabric employed and/or the types of cells to be immobilized, it would have been obvious to one of ordinary skill in the art to surface treat the carrier material so as to ensure the attachment of the cells to the carrier.

With respect to claims 22 and 32, the reference discloses the use of a plurality of chambers (See Figures 1, 7 and 8).

With respect to claims 23, 24, 30 and 31, the reference discloses the use of probes and pH and oxygen concentration control (See Figure 1 and page 9 of the translation).

With respect to claim 25, the housing includes an inlet and outlet for the flow of culture medium.

With respect to claim 26, the disclosed device is employed as a cell culture device and meets the method steps of claim 26.

With respect to claim 27, the reference discloses a sterilization step (See page 11 of the translation).

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7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katinger et al.(DE 0155237) in view of Rotman (US 4,734,372) or Wilhelm (US 5,190,878).

The reference of Katinger et al. has been discussed above.

Claim 21 differs by reciting that the device is circular.

The references of Rotman and Wilhelm both disclose that it is known in the art to provide bioreactor devices as flat cells that are circular (See the figures of both references).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the device of the reference of Katinger et al. in a circular shape for the known and expected result of providing an alternative shape recognized in the art for providing a perfusion bioreactor device.

8. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katinger et al.(DE 0155237) in view of Palsson et al.(US 5,688,687).

The reference of Katinger et al. has been discussed above.

Claim 28 differs by reciting that the method includes using a chemical agent to release the attached cells.

The reference of Palsson et al. discloses that it is known in the art to harvest cells from a culture chamber by introducing harvesting reagents into the culture chamber (See column 8, lines 32-47).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to harvest cells from the primary reference of Katinger et al. at

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the completion of culture using the reagents disclosed by Palsson et al. for the known and expected result of harvesting the cultured cells.

9. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Katinger et al.(DE 0155237) in view of Takahata et al.(JP 57-166985).

The reference of Katinger et al. has been discussed above.

Claim 29 differs by reciting that the flow of media is reversed in the device.

The reference of Takahata et al. discloses that it is known in the art to reverse the flow of culture medium in a membrane bioreactor device so as to removing clogging materials from the membrane.

In view of the this teaching, it would have been obvious to one of ordinary skill in the art to reverse the flow of medium in the system of Katinger et al. for the known and expected result of preventing clogging of the membranes within the bioreactor device.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The references of Feder et al.(US 4,201,845); Puchinger et al.(US 4,225,671); Naughton et al.(US 6,218,182); and Kersten et al.(US 6,228,607) are cited as prior art that pertains to membrane bioreactor devices.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 703-308-4006. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:40am to 4:10pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 703-308-2920. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



William H. Beisner
Primary Examiner
Art Unit 1744

WHB